Amendment #4
to RFP-NIH-NIAID-DMID-03-32

"Antibody Production Facility"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-32
Amendment No.:	4
Amendment Date:	November 5, 2002
RFP Issue Date:	September 20, 2002
Issued By:	Elizabeth Osinski Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Elizabeth Osinski, Contract Specialist
Name and Address of Offeror:	To All Offerors

RFP-NIH-NIAID-DMID-03-32 is amended as follows:

Add a Note 10 to the RFP as follows:

Note 10 - Reference - Statement of Work, item 4a. Validate and perform assays, including but not limited to, measure affinity, thermal and denaturant stability, serum half-life, and neutralization activity of the Abs selected, including relevant animal protection assays if appropriate.

For purposes of both the cost and technical evaluation, prospective offerors shall not include in their proposal either in vitro or in vivo assays to measure antibody neutralization activity (See Statement of Work, item 4a above). Offerors shall propose activities related to physical and chemical characterization, including but not limited to, thermal and denaturant stability. NIAID will work with the successful offeror after award either through arrangements with other Government laboratories or other NIAID animal models contracts to provide for evaluation of antibody activity."

Item (10) as set forth below is added to the RFP in Section L.2.c. Business Proposal Instructions:

(10) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in

the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Page 19, Reporting Requirements Paragraph B. – Semi-Annual Technical Reports, is corrected to read as follows:

Semi-Annual Technical Progress Reports – by the fifteenth working day of the month following the end of each six month period, the Contractor shall submit three (4) copies of a semi-annual Technical Progress Report, comprising two (3) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information.

1. Reference: Note 1

Question: The RFP requires the Contractor to produce Abs for clinical trials, but states that the cost of conducting trials will not be incurred by the APF and should not be included in the offerors cost proposal. Other than simply providing Abs, does the Agency contemplate that the Contractor will have any role in clinical trials? If so, please describe the anticipated Contractor roles and responsibilities.

The Contractor will be required to provide information necessary for filing the IND and preparing the Investigators Brochure. Please refer to Statement of Work, Paragraph a, item 8.j. on page 6 of the RFP. Also, please refer to Note #1, in Amendment #1 to the RFP.

2. Reference: Introduction/Background, paragraph 4 and Instructions for Submission of Task Orders, paragraph 5.

Question: Recognizing this is a requirements contract, is there more information available regarding the types and sequence of products that may be required?

Please refer to page 10, Note #9 of the RFP and SECTION L., paragraph e. of this RFP. This is what is anticipated at this time. I have reprinted it below.

Note 9: The estimated quantities to be procured by this Requirements contract are set forth below and are also set forth in SECTION L., Paragraph e. of this RFP. **Offerors are advised that the quantities listed below are only estimates and the Government will be issuing Task Orders that may vary from these estimates.**

It is anticipated that the following quantities will be procured under this RFP:

PART A

- Year 1 – 2 monoclonal antibodies
- Year 2 - 2 to 4 monoclonal antibodies
- Year 3 – 2 to 4 monoclonal antibodies

- Option Year 4 – 2 to 4 monoclonal antibodies
- Option Year 5 – 2 to 4 monoclonal antibodies
- Option Year 6 – 2 to 4 monoclonal antibodies
- Option Year 7 – 2 to 4 monoclonal antibodies

PART B

- 100,000 adult doses total – Years 1 through 3
- 50,000 adult doses per year Option Years 4, 5, 6, and 7

3. Reference: Note 2

Question: The RFP states that offerors "may propose their own products (or products contributed by their proposed subcontractors if they have been shown to be effective in pre-clinical or clinical trials." Would an offeror that proposes its own products (or those of a subcontractor) be treated any differently in the evaluation from one that did not propose any of its own (or a subcontractor's) products?

Section M – Evaluation Factors for Award, item 4, Technical Evaluation Criteria, lists the evaluation criteria and the weights for each criterion. The proposal will be evaluated in accordance with the criteria as set forth in the RFP.

4. Reference: Note 9 and Section L.1.e.

Question: The RFP provides certain estimates of doses. We understand that the contract will be a requirements contract and that task orders may vary from stated estimates, but does the Agency have an estimated range (minimum-maximum) of its potential requirements?

Please refer to Question #2 above and Note #9 in the RFP.

5. Reference: Note 9 and Section L.1.e.

Question: Please clarify the relationship between "Part A" and "Part B." Are we to assume that these correspond to the A and B headings in the Statement of Work? If so, do the "Part B" estimates indicated in Note 9 and Section L.1.e. pertain to Task 3 (Stockpile)?

Part A in the Statement of Work is for the production of antibodies for Phase I/II Clinical Trials and Part B in the Statement of Work is for producing antibodies to deposit in the National Pharmaceutical Stockpile. Part A and Part B do correspond to the A and B headings in the Statement of Work. The Part B estimates indicated in Note 9 and Section L.1.e. do pertain to the National Stockpile which is part of Task 3; however, Task 3 with the 100,000 doses is only a Sample Task.

6. Reference: Part II, Article I.1. b

Question: Has the Agency considered indemnifying the Contractor under authority of Pub. L. 85-804 in light of the potentially high costs of the insurance for the scope of work required by the contract? If so, which risks might be covered by an indemnification clause?

Subsequent to award the Contractor has the right to submit a request in accordance with FAR Subpart 50.403 - Special Procedures for Unusually Hazardous or Nuclear Risks. FAR 50.403-1 lists the information that must be included in Indemnification Requests. This request must be approved by the Secretary of DHHS. It is the responsibility of the Contractor to identify which risks might be covered by an indemnification clause.

7. Reference: Reporting Requirements, B. and B.4.

Question: Please clarify the number of copies of the Semi-Annual Technical Progress Report to be delivered to the Project Officer. The requirement in the opening paragraph states two (2) copies" (totaling 3 copies of the report) and the requirement in #4 states "three (3) copies" (totaling 4 copies of the report).

The appropriate sections of the RFP have been corrected in this amendment. Four (4) total copies of the report will be required.

The hour and date specified for receipt of offers is NOT extended.

Offerors must acknowledge receipt of this Amendment #4, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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